

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

THIS DOCUMENT RELATES TO:

All Suits Against the Saint Thomas Entities

MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)

**SAINT THOMAS ENTITIES' RESPONSE IN OPPOSITION TO PSC'S MOTION TO
COMPEL REGARDING CERTAIN DOCUMENT REQUESTS**

The Saint Thomas Entities¹ hereby file their response in opposition to the PSC’s motion to compel responses to certain document requests [Dkt. No. 1664]. The PSC’s motion seeks to compel the production of two documents: (1) a non-redacted version of the St. Thomas Hospital (“STH”) Formulary; and (2) an index of all “policies and procedures” applicable to the Saint Thomas Entities.² For the reasons explained below, the PSC seeks to enforce overly broad discovery requests and compel production of documents that lack any relevance to the claims or defenses at issue in this litigation. Accordingly, the PSC’s motion to compel should be denied.

I. BACKGROUND

1. Plaintiffs allege injuries and death based on contaminated epidural injections manufactured and sold by the New England Compounding Center (“NECC”).³ Plaintiffs have made claims against numerous non-NECC parties, including the Saint Thomas Entities and Saint Thomas Outpatient Neurosurgical Center (“STOPNC”).⁴ STOPNC allegedly purchased

¹ Saint Thomas West Hospital f/k/a St. Thomas Hospital; Saint Thomas Health; and Saint Thomas Network.

2 Mot. to Compel at 8.

³ See Mem. of Decision [re: Motions to Dismiss] (August 29, 2014) [Dkt. No. 1360].

4 *Id.* at 2.

contaminated medication from NECC and administered them to patients.⁵ The Saint Thomas Entities include Saint Thomas Health (“STHe”), which is an owner of Saint Thomas Network (“STN”), which in turn is a co-owner of STOPNC.⁶ Plaintiffs assert that STOPNC is the agent of one or more of the Saint Thomas Entities and that the Saint Thomas Entities should be held vicariously liable for STOPNC’s alleged acts or omissions.⁷

2. Plaintiffs allege that Defendants John Culclasure, M.D. and Debra Schamberg co-managed STOPNC’s day-to-day operations.⁸ Plaintiffs assert that Dr. Culclasure and Ms. Schamberg were directly involved and responsible for STOPNC’s decision to purchase methylprednisolone acetate (“MPA”) from NECC.⁹ Plaintiffs allege that STOPNC, Dr. Culclasure, and Ms. Schamberg decided to purchase MPA in bulk from NECC because it was the cheapest steroid, and that STOPNC did not conduct appropriate due diligence or investigation into NECC before deciding to purchase and administer NECC-compounded steroids to their patients.¹⁰

3. Plaintiffs allege that, from 2000 to the present, the “medication formulary for [STOPNC] lists those steroids acceptable for use at [STOPNC] and includes: Decadron, Depo-medrol, Solumedrol and Celestone Soluspan.”¹¹ Plaintiffs assert that the “[STOPNC] formulary does not include generic [MPA] or MPA from a compounding company as acceptable for use at [STOPNC][,]” but that it does include and allow for the administration of MPA manufactured by

⁵ *Id.* at 3.

⁶ *Id.* at 4.

⁷ *Id.*

⁸ See Orig. Compl. at ¶ 128, *Reed v. Ameridose*, No. 1:13-cv-12565-RWZ [Dkt. No. 1]. The PSC refers to the Original Complaint filed in *Reed* as a representative complaint containing allegations against the Saint Thomas Entities for purposes of the PSC’s motion, as the Saint Thomas Entities are not named in the Master Complaint. See Mot. to Compel at 4 n.16. Accordingly, the Saint Thomas Entities will also refer to the *Reed* complaint in this response (“*Reed* Complaint”).

⁹ See *Reed* Compl. at ¶ 129.

¹⁰ *Id.* at ¶¶ 132–133.

¹¹ *Id.* at ¶ 139.

Pfizer under the name Depo-medrol.¹² Plaintiffs allege that, in making the decision to purchase compounded MPA from NECC, Dr. Culclasure and Ms. Schamberg failed to follow the medication formulary adopted by STOPNC.¹³ A copy of the formulary produced by STOPNC is attached to the *Reed* Complaint, and is attached hereto as Exhibit A.¹⁴ It is undisputed that the formulary attached to the *Reed* Complaint and re-attached here is a true and correct copy of STOPNC's formulary.¹⁵

4. Plaintiffs allege that STN and STHe acted in concert with HAC to jointly operate STOPNC, and conclusorily assert that STN and STHe failed to reasonably supervise STOPNC's drug procurement practices, failed to "implement or enforce policies and procedures that would prevent the procurement of purportedly sterile injectable medications" from NECC, and "approved, facilitated or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives"¹⁶ Notably absent is *any* allegation that STOPNC was governed by STH's Formulary or any of the Saint Thomas Entities' policies. To the contrary, it is undisputed that STOPNC had its own formulary and followed its own set of policies. *See, e.g.,* Transcript Excerpt at 25:12–26:10, Feb. 4, 2015 Deposition of D. Schamberg, attached hereto as Exhibit B.¹⁷

¹² *Id.* at ¶¶ 140–141.

¹³ *Id.* at ¶ 258; *see also id.* at ¶ 259(h) ("Specifically, Dr. Culclasure and Ms. Schamberg were negligent and rendered substandard care . . . [by] fail[ing] to follow [STOPNC's] own formulary that would have prevented the use of MPA compounded by NECC in epidural steroid injections").

¹⁴ *Id.* at ¶ 142.

¹⁵ *See* Answer of STOPNC, HAC, Dr. Culclasure, and Debra Schamberg at ¶ 142, *Reed v. Ameridose*, No. 1:13-cv-12565-RWZ [Dkt. No. 42-1].

¹⁶ *Id.* at ¶¶ 278, 281(g), (l), (n).

¹⁷ Counsel for the Saint Thomas Entities conferred with counsel for Debra Schamberg regarding the attached deposition excerpt. Counsel for Ms. Schamberg consented to the filing of the attached deposition excerpts without seal subject to, and without waiver of, Ms. Schamberg's right to designate other portions of the deposition transcript as confidential pursuant to the Deposition Protocol (MDL Order No. 10) [Dkt. No. 1426] and the Third Amended Protective Order of Confidentiality [Dkt. No. 814].

5. On November 19, 2014, the PSC moved to compel the Saint Thomas Entities to respond to certain interrogatories [Dkt. Nos. 1549 & 1550]. After conducting several meet-and-confer discussions with the PSC, the parties reached agreements regarding the PSC's motion to compel, and the Saint Thomas Entities agreed to supplement their initial interrogatory responses prior to necessitating the Court's involvement. As part of this process, the Saint Thomas Entities produced portions of the STH Formulary that referenced methylprednisolone and produced the applicable policy relating to drug procurement at STH. On January 13, 2015, the PSC withdrew the then-pending motion to compel [Dkt. No. 1636].

6. The Saint Thomas Entities agree with the PSC that two issues arising out of the meet-and-confer discussions remained in dispute at the time the motion to compel was resolved. Contrary to the PSC's motion, however, the Saint Thomas Entities have never taken the position that "a substantive response to certain interrogatories is not necessary due to relevancy or breadth." To the contrary, the Saint Thomas Entities have already provided substantive interrogatory responses, and the documents sought by the PSC are not responsive to the interrogatories at issue in the prior motion to compel.¹⁸ See Dec. 19, 2014 letter from A. Schramek to B. Gastel, attached hereto as Exhibit C.

7. Specifically, the Saint Thomas Entities informed the PSC that its request for a "compilation of pharmaceuticals" does not contain any information from which an answer to Interrogatory 11 to STH may be derived. See *id.* The Saint Thomas Entities advised that, in particular, Interrogatory 11 sought an explanation of STH's "policies and procedures regarding the purchase of medications" *Id.* The Saint Thomas Entities stated that, in response, they

¹⁸ Indeed, the sole interrogatory response quoted by the PSC's motion is a "substantive" response explaining how STH generally purchased medications, and identifying and attaching applicable policies related to pharmacy procurement. It remains unclear whether the PSC's motion to compel concerns certain document requests—as suggested by the motion's title and citations to requests for production—or the PSC's interrogatories.

provided the STH Formulary System policy, “which explains the policies and procedures for a medication to be approved for use at the Hospital, as well as the name of the Hospital’s group purchasing organization.” *Id.* The Saint Thomas Entities advised that the procedure for approving a medication is not the same thing as the list of approved medications, and that “a list of medications would tell [the PSC] nothing about the approval process.” *Id.* at 1–2. Nonetheless, putting aside the fact that the STH Formulary—the list containing the generic and brand name drugs approved for use at STH—does not contain any information responsive to the PSC’s interrogatory, the Saint Thomas Entities agreed to produce potentially relevant portions of the STH Formulary as a showing of good faith and in an attempt to move past the interrogatory dispute. *See id.* at 2.

8. The Saint Thomas Entities also reiterated their position that, since the lawsuits against them solely concern injections that occurred at STOPNC and patients treated at STH, medication policies or procedures unrelated to STH were not relevant to any claim or defense. *See id.* The Saint Thomas Entities further noted that many of the PSC’s interrogatories were overly broad and unduly burdensome and while the Saint Thomas Entities have attempted to reasonably limit them, much of the information sought is more appropriate for deposition testimony. *See id.* Instead of withdrawing their demands for irrelevant and overly broad information, the PSC now requests production of the remaining portions of the STH Formulary and a list of all of the Saint Thomas Entities’ respective Policies and Procedures under the misguided belief that such documents will lead to the discovery of relevant or admissible evidence. The PSC’s requests are without merit.

II. ARGUMENT

A. The Withheld Portions of the STH Formulary are Entirely Irrelevant to this Litigation

1. *The PSC has identified no request calling for the STH Formulary, and the Saint Thomas Entities object to producing an unredacted version.*

The non-produced portions of the STH Formulary are not responsive to any discovery request and are completely irrelevant to the claims and defenses asserted in this litigation. As noted above, the Saint Thomas Entities originally relied on their objections in withholding production of the Formulary, but subsequently agreed to provide a redacted version in a good faith effort to compromise with the PSC and to avoid unnecessarily involving this Court. *See* STH Formulary (Redacted), attached hereto as Exhibit D.¹⁹ The portions of the Formulary that were produced consist of the Formulary's headings and the Formulary entries related to methylprednisolone. *See id.* The entries consist of generic drug descriptions (e.g., "methylprednisolone 16 mg tab"); brand name (e.g., "SOLU-MEDROL"), and therapeutic class, for which all of the methylprednisolone entries are encompassed in the "steroids, adrenal cortical" class. *See id.* As it is undisputed that none of the Saint Thomas Entities administered any NECC MPA, and that STOPNC was governed by its own formulary, the STH Formulary does not contain information relevant to this litigation.

The produced portion of the Formulary shows, however, that the information the PSC contends it would find in the unredacted version is illusory. The Formulary does not contain any columns identifying whether a drug is compounded or whether a compounded version of a drug can be purchased. Basic logic indicates further that compounding would not be addressed in any

¹⁹ The STH Formulary was modified at least three times in 2012. Accordingly, the Saint Thomas Entities produced Formulary excerpts for the four versions that existed closest in time to the meningitis outbreak. *See* Ex. C. at 2. The Saint Thomas Entities have attached the February 22, 2012 version of the Formulary for illustrative purposes, but will supplement if the Court wishes to review the other three versions.

of the other columns. The “Description (Generic)” column contains just that—the generic names for drugs included in the STH Formulary. Likewise, the “Therapeutic Class” column contains general classes of drugs, such as “vitamins” and “topical anesthetics.” And the “Brand Name” column consists of specific brands manufactured by pharmaceutical manufacturers. The Formulary does not list the manufacturers affiliated with the brands, does not identify any other information relating to the source of the listed drugs, and contains no limitations regarding the purchase of generic versus brand-name drugs.²⁰ In fact, the Formulary does not mention or refer to compounded products at all.

Accordingly, even if the Saint Thomas Entities’ understanding of the “risks associated with compounded pharmaceuticals”²¹ were relevant to this litigation—which it is not—the excerpted portions of the STH Formulary that were produced previously show that the Formulary will in no way “shed light” on the Saint Thomas Entities’ beliefs about compounded pharmaceuticals. Similarly, the produced portions of the STH Formulary demonstrate that the PSC’s speculation that the Formulary is “one of the key pieces of evidence showing how [STH] treats compounded pharmaceuticals as it relates to their FDA regulated equivalents[]” is misplaced. As noted above, the STH Formulary does not address or reference compounded pharmaceuticals.

In any event, to the extent the PSC seeks the production of the entire STH Formulary in an attempt to show that any absence of approved compounded products on the Formulary is somehow indicative of the Saint Thomas Entities’ beliefs as to the risks associated with compounded products, the Saint Thomas Entities are more than willing to stipulate or respond to

²⁰ Such limitations, if they existed in the Formulary, could arguably relate to compounded products, as a compounding pharmacy would only be able to compound a generic drug. The brand-name drug would be manufactured by the manufacturer that created the brand.

²¹ See Mot. to Compel at 9.

a request for admission stating that the STH Formulary does not, and did not in 2012, make any reference to compounded products.

In a last-ditch effort to argue that the remaining portions of the STH Formulary are somehow relevant to this litigation, the PSC argues that “if it can be shown that the purchase of MPA by [STOPNC] was not in accordance with [STH’s] formulary, that is strong evidence of the Saint Thomas Entities’ failure to adequately supervise its agent’s purchase of same.”²² This fact is already undisputed. *See* Ex. B, Schamberg Depo. Tr. at 25:12–26:10. STH’s Formulary in no way governed or applied to STOPNC’s purchases of medication, and therefore, STOPNC’s purchase of MPA could not possibly have been “in accordance” with STH’s Formulary. *See id.*

In short, the PSC has failed to identify any discovery request to which the STH Formulary is responsive and the portions STH refused to voluntarily produce are entirely irrelevant to this litigation. The PSC has failed to identify an argument to the contrary. A discovery request for the entire Formulary would be overly broad and not reasonably calculated to lead to the discovery of relevant evidence regarding any allegation in the Complaints, and should therefore be denied.

B. The PSC’s Demand for an Index of Policies and Procedures is No More than a Fishing Expedition

1. *The Saint Thomas Entities have produced potentially relevant policies and object to producing indexes of all policies and procedures.*

As noted above, the Saint Thomas Entities previously produced policies related to the procurement of medication at STH and objected to the production of other types of policies unrelated to STH medication procurement. The PSC contends that the Saint Thomas Entities should now be compelled to produce “a copy of an index of *all* of its [sic] policies and

²² *See* Mot. to Compel at 10.

procedures that would help the PSC evaluate which policies may be applicable in this case.”²³

The PSC’s request is nothing more than a classic fishing expedition.

The PSC has attempted to premise its request for the indexes of the policies and procedures of the respective Saint Thomas Entities as relating to the PSC’s vicarious liability claims against the Saint Thomas Entities. The PSC appears to argue that, because policies may contain definitions of “Saint Thomas Health,” “Saint Thomas Hospital,” and “Saint Thomas Network,” they are “highly relevant to establishing the facts supporting vicarious liability claims.”²⁴ However, the PSC did not request any policies containing such definitions. Instead, it sent an overly broad request for “all” policies and procedures, regardless of subject matter. The Federal Rules of Civil Procedure do not permit a party to send an overly broad request and then define what it really wants on the back end, in the context of a motion to compel.

The Saint Thomas Entities have already produced more than 36,036 pages of documents in this litigation, most of which were produced pursuant to electronic search terms agreed upon by the parties. These parties have also produced an organizational chart showing the relationship among the Saint Thomas Entities and between the Saint Thomas Entities and STOPNC. The PSC has more than enough documents in its possession to “investigate the internal workings of the Saint Thomas Entities,”²⁵ and its request for a policy index so that it can identify policies that might potentially touch on the definitions of the respective Saint Thomas Entities is improper. The Federal Rules of Civil Procedure do not permit such blatant fishing expeditions. *See, e.g., Ortiz v. Baird*, No. 10-1753, 2012 WL 1391649, at *3 (W.D. Pa. Apr. 20, 2012) (describing

²³ *Id.* (emphasis added). Curiously, although the parties had only discussed the PSC’s request for STHe policies during their meet-and-confer discussions, the PSC now apparently seeks to compel the production of indexes of all of policies and procedures of the Saint Thomas Entities, which would consist of separate indexes for STHe, STH, and STN. *See* Mot. to Compel at 12 (“[T]he PSC respectfully requests that the Court compel the Saint Thomas Entities to produce . . . [a]n index of all of Saint Thomas Entities’ policies and procedures.”).

²⁴ *See* Mot. to Compel at 11.

²⁵ *See id.* at 12.

plaintiff's request for copies of defendants' "master index procedural manual" so that plaintiff could search for "any policies that may be relevant to his claims[,] as overbroad and "the quintessential fishing expedition").

The PSC also contends that it is "nearly impossible" for the PSC to determine what policies and procedures could be applicable to Plaintiffs' claims without knowing the universe of such policies and procedures. This is simply untrue. It is undisputed that the lawsuits at issue concern STOPNC's purchase of contaminated MPA from NECC. STOPNC had its own policies and procedures concerning the purchase of medication, which have been produced. The Saint Thomas Entities likewise produced their policies and procedures applicable to the procurement of compounded pharmaceuticals. To the extent that other potentially relevant policies exist that the Saint Thomas Entities have not already produced, however, presumably the 36,036 or more pages of documents produced by the Saint Thomas Entities in this litigation would likely reference such policies. Similarly, to the extent any policy references STOPNC, the electronic search terms agreed upon by the parties would likely result in the production of any such policy.

The PSC nevertheless states that STHe "may have specific policies regarding the purchase of compounded pharmacists [sic] or specific policies regarding the management of joint ventures and co-owned facilities like [STOPNC]."²⁶ This argument lacks merit. As noted above, the relevant procurement policies have already been produced. With respect to "joint venture management" policies, STOPNC and the Saint Thomas Entities have produced the specific agreements pursuant to which STOPNC is operated (by Howell Allen Clinic, not the Saint Thomas Entities). Once again, if the PSC wants to confirm that no "joint venture management" policies exist—which they do not—it can propound a request for admission. Or it can send a narrowly tailored document request asking for any such policy. What it cannot do is

²⁶ Mot. to Compel at 11.

send an overly broad request for “all policies and procedures” and then define what it wants in a motion to compel.

Finally, the PSC argues that such indexes are routinely produced in medical malpractice actions “in this state” and that the Saint Thomas Entities’ refusal to do so is simply unsupported.²⁷ It is the PSC’s argument, however, that is not supported by any citations or other basis in the law. On the other hand, opinions from several federal cases explain that a request for an index of all policies is overly broad and an impermissible fishing expedition under the Federal Rules of Civil Procedure. *See, e.g., Morrow v. Straughn*, No. 5:13-cv-00135, 2014 WL 69048, at *1 (E.D. Ark. Jan. 8, 2014) (denying plaintiff’s motion to compel discovery of defendants’ policy and procedure index as overly broad); *Ortiz*, 2012 WL 1391649, at *3 (same); *Perry v. City of Pontiac*, No. 07-14036, 2011 WL 4345239, at *4 (E.D. Mich. Sept. 16, 2011) (rejecting plaintiffs’ attempt to compel discovery of copy of index of defendants’ general operating procedures where defendants had already produced rules and regulations relevant to suit’s subject matter).

A party may not “undertake wholly exploratory [discovery] operations in the vague hope that something helpful will turn up.” *See Mack v. Great Atl. & Pac. Tea Co., Inc.* 871 F.2d 179, 187 (1st Cir. 1989). It likewise may not “go on a fishing expedition, with the mere hope that it will obtain” relevant information. *See Ameristar Jet Charter, Inc. v. Signal Composites, Inc.*, 244 F.3d 189, 193 (1st Cir. 2001) (citation and internal quotation marks omitted). The PSC’s requests for policy indexes and the entire STH Formulary are improper and should be denied.

²⁷ The Saint Thomas Entities assume that “this state” is intended to refer to the State of Tennessee.

III. CONCLUSION

WHEREFORE, the Saint Thomas Entities respectfully request that the Court deny the
PSC's motion to compel.

Dated: February 9, 2015

By their attorneys,

/s/ Sarah P. Kelly
Sarah P. Kelly (BBO #664267)
skelly@nutter.com

NUTTER McCLENNEN & FISH LLP
Seaport West
155 Seaport Boulevard
Boston, Massachusetts 02210
(617) 439-2000
(617) 310-9461 (FAX)

OF COUNSEL:

Yvonne K. Puig*
Texas State Bar No. 16385400
yvonne.puig@nortonrosefulbright.com
Adam T. Schramek*
Texas State Bar No. 24033045
adam.schramek@nortonrosefulbright.com
Eric J. Hoffman*
Texas State Bar No. 24074427
eric.hoffman@nortonrosefulbright.com

NORTON ROSE FULBRIGHT US LLP
98 San Jacinto Blvd., Suite 1100
Austin, Texas 78701
(512) 536-2450
(512) 536-4598 (FAX)

Marcy Hogan Greer*
Texas State Bar No. 08417650
mgreer@adjtlaw.com

ALEXANDER DUBOSE JEFFERSON &
TOWNSEND LLP
515 Congress, Suite 2350
Austin, Texas 78701
(512) 482-9300
(512) 482-9303

*Appearing Pro Hac Vice

CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing this 9th day of February, 2015.

/s/ Sarah Kelly

Sarah P. Kelly